HIT Policy Committee
Adoption/Certification Workgroup

February 25, 2010

9:00 a.m. – 3:00 p.m. (Eastern)
OMNI Shoreham Hotel
2500 Calvert Street, NW
Washington, DC 20008

Instructions and Questions for Panelists

Background

Testimony from this hearing will help the Adoption/Certification Workgroup formulate recommendations to the HIT Policy Committee and National Coordinator on patient-safety issues related to use of electronic health records – both risks and approaches to mitigating those risks. If you have any questions, please contact Kathy Kenyon at Kathy.Kenyon@hhs.gov

Format of Presentation:

The Workgroup respectfully requests that panelists limit their prepared remarks to 5-7 minutes. This will allow the Workgroup to ask questions of the panelists and allow every presenter time to present his or her remarks. We have found that this creates a conversation for a full understanding of the issue. You may submit as much detailed written testimony as you would like, and the Workgroup members will have reviewed this material in detail before the hearing. PowerPoints will not be needed.

Pre-Presentation Questions/Themes:

The questions below represent areas the Workgroup intends to explore at the hearing. Please feel free to use them in preparing your oral and written testimony; the Workgroup recognizes that certain questions may not apply to all presenters.

The Workgroup respectfully requests panelists to provide written testimony by **February 19, 2010**. Please submit the testimony to Kathy Kenyon and Judy Sparrow at Kathy.kenyon@hhs.gov and Judy.sparrow@hhs.gov

Presenter Biography

In addition, the Workgroup requests that all presenters provide a short bio for inclusion in the meeting materials. Please send your short bios to Judy Sparrow, judy.sparrow@hhs.gov

THEMES/QUESTIONS

Panel 1: Identifying the Issues

What are patient-safety risks that may be introduced inadvertently through the use of electronic health records (EHRs) or other HIT products? Are there specific types of risks that are more common than others?
What are the causes of those risks?
What are ways to prevent and/or mitigate those risks?
How would you weigh the benefits and risks of using EHRs in patient care?
How might data on risks best be identified as greater HIT adoption occurs?
What are the factors that might impact an organization from reporting adverse events or known concerns about HIT products?

Panel 2: Stakeholders

What experiences have you had with EHR-associated patient safety risks?
How have you identified those risks?
What steps have you taken to prevent harm or to mitigate the safety risks?
What approaches would you recommend to prevent or mitigate harm associated with the use of EHRs?
What are the benefits and concerns about making those risks and/or adverse events publicly known?

Panel 3: Possible Approaches

General Question: What approaches would you recommend policy-makers and the health care industry consider to address safety issues? How might these approaches affect innovation, timing of getting products to market, costs, etc.?

If you are a government representative:

- Describe the current status of regulatory activities or other programs related to patient safety, including your legal authority.
- Describe considerations that may impact government efforts in the future.
- Describe approaches for reporting and tracking patient safety concerns and addressing these concerns.

If you are conducting research and evaluation of safety issues related to EHRs:

- Describe main options for activities by government and private entities to address safety concerns regarding EHR, including reporting.
- Describe advantages and disadvantages of different approaches.

Industry Perspective:

- Describe organizations or processes you rely upon to have confidence you are buying a safe EHR?
- What approaches to EHR safety would give users confidence?
- What do EHR vendors do with customer-reported safety issues? How are other customers notified of potential issues? What is the counterpart to product recalls and notifications to customers?
- What are the advantages and disadvantages of government regulation?
- What are the advantages and disadvantages of private, voluntary programs to certify safety?
- What role should safety reporting have? Who should receive such reports? What are the characteristics of an organization that receives EHR safety reports? How should the aggregate data be used? How should the findings and recommendations be disseminated?